



05-29-07

IFU

CASE BP/G-32574A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT NATIONAL STAGE APPLICATION OF

BETZ ET AL.

INTERNATIONAL APPLICATION NO: PCT/EP03/07347

FILED: 8 JULY 2003

U.S. APPLICATION NO: 10/520,569

35 USC §371 DATE:

FOR: LIQUID FORMULATIONS WITH HIGH CONCENTRATION OF
HUMAN GROWTH HORMONE (HGH) COMPRISING PHENOL

MS: Amendment

Commissioner for Patents

PO Box 1450

Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

This paper is supplemental to the Information Disclosure Statement filed January 7, 2005. Since Applicants believe this paper is being filed before the mailing date of a first Office Action on the merits, no fees are believed to be required under 37 C.F.R. §1.97(b)(3). If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-0134.

In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

Copies of these references are enclosed herewith.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Mark J. Bowditch', written over a horizontal line.

Mark Bowditch
Attorney for Applicants
Reg. No. 40,315

Novartis
Corporate Intellectual Property
One Health Plaza, Building 104
East Hanover, NJ 07936-1080
(609) 627-8507

Date: 5/25/07

INFORMATION DISCLOSURE CITATION

(Use separate sheets if necessary)

ATTY. DOCKET NO.
BP/G-32574A
APPLICATION NO.
10/520,569
APPLICANT
BETZ ET AL.
FILING DATE

Group



U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE |
|---------------------|----|-----------------|----------|-----------------|-------|----------|-------------|
| | AA | 5,981,485 | 11/9/99 | O'connor et, al | | | |
| | AB | 4,637,834 | 1/20/87 | Thurrow | | | |
| | AC | 4,783,441 | 11/8/88 | Thurrow | | | |
| | AD | 5,374,620 | 12/20/94 | Clark et, al | | | |
| | AE | 5,597,802 | 1/28/97 | Clark et, al | | | |
| | AF | | | | | | |
| | AG | | | | | | |
| | AH | | | | | | |
| | AI | | | | | | |
| | AJ | | | | | | |
| | AK | | | | | | |
| | AL | | | | | | |

FOREIGN PATENT DOCUMENTS

| | | DOCUMENT NUMBER | DATE | OFFICE | CLASS | SUBCLASS | TRANSLATION | |
|--|----|-----------------|----------|----------------------|-------|----------|--------------------------|--------------------------|
| | | | | | | | YES | NO |
| | AM | WO 2001/03741 | 1/18/01 | Grandis Biotech GMBH | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | AN | WO 1993/19776 | 4/1/93 | Pharmacia Artiebolar | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | AO | WO 1993/12811 | 12/16/92 | Novo Nordisk | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | AP | WO 1993/19776 | 4/1/93 | Kabi Pharmacia | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | AQ | WO 1991/14454 | 4/2/91 | Skua Investments Ltd | | | <input type="checkbox"/> | <input type="checkbox"/> |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

| | | |
|--|----|--|
| | AR | Isosmotic and Isotonic Solutions |
| | AS | Jorgensen et al, "Patent Acceptance of Nordiject: A new drug delivery system for growth Hormone" |
| | AT | R. Pearlman & T. Bewley " Stability and Characterization of Human Growth Hormone" |

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)



ATTY. DOCKET NO.
BP/G-32574A
APPLICATION NO.
10/520,569
APPLICANT
BETZ ET AL.
FILING DATE

Group

EXAMINER
INITIAL

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

| | |
|----|---|
| DA | Physicians Desk Reference - Pages 989-990 |
| DB | Journal of Parenteral Science and Technology, Technical Report 10 |
| DC | Physicians Desk Reference - Pages 1940 & 1941 |
| DD | K.H. Wellh         "Pharma -Technik" pgs 716-722 |
| DE | S.P. Denyer et, al " Antimicrobial preservatives and their properties", pgs 252-272 |
| DF | Sean Evans and Peter Grassam " Considerations for Parenteral Dosage Form Development of Natural Alpha Interferon, pgs 83-87 |
| DG | Alfonso Gennaro, Remington Pharmaceutical Sciences , pages 1549-1550 |
| DH | |
| DI | |
| DJ | |
| DK | |
| DL | |
| DM | |
| DN | |

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)



ATTY. DOCKET NO.
BP/G-32574A
APPLICATION NO.
10/520,569
APPLICANT
BETZ ET AL.
FILING DATE

Group

FOREIGN PATENT DOCUMENTS

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | OFFICE | CLASS | SUBCLASS | TRANSLATION | |
|---------------------|----|-----------------|---------|-------------------------|-------|----------|--------------------------|--------------------------|
| | | | | | | | YES | NO |
| | CA | WO 1994/ 03198 | 7/29/93 | Genentech, Inc | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CB | WO 1991/11200 | 1/25/91 | Janssen Pharmaceutica | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CC | EP 0 938 902 | 9/1/99 | JCR Pharmaceuticals Inc | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CD | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CE | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CF | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CG | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CH | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CI | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CJ | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CK | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CL | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CM | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CN | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CO | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CP | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CQ | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CR | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CS | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CT | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CU | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CV | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CW | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CX | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CY | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | CZ | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.